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Appl. No. 09/960,749  
Amendment dated September 24, 2003  
Reply to Office Action mailed June 5, 2003

REMARKS

Summary of Office Action

Applicants' election with traverse of the claims in Group IV as identified by the Examiner was acknowledged.

Claims 28-38 are pending in the above-identified patent application.

The drawings were objected to as failing to comply with 37 C.F.R. 1.84(p)(5) because reference signs 14, 15, 20, and 242 are not mentioned in the description.

Claims 28, 33, and 35 were objected to because of minor informalities.

Claims 28-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28, 30, and 31-33 were rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,152,144 to Lesh et al. ("Lesh").

Claims 28-31 and 34-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh in view of U.S. Patent No. 5,797,960 to Stevens et al. ("Stevens").

Summary of Applicants' Reply

Applicants have amended the specification and FIG. 1 to address the Examiner's objections to the drawings. Claims 28-35, 37, and 38 have been amended to more particularly point out and distinctly claim the subject matter of applicants' invention. Claim 36 has been canceled without prejudice. New claims 39 and 40 have been added to more particularly point out and distinctly claim subject matter of applicants' invention. The Examiner's objections and rejections are respectfully traversed.

Drawings and Specification

The Examiner objected to the drawings as failing to comply with 37 C.F.R. 1.84(p)(5) because reference numerals 14, 15, 20, and 242 are not mentioned in the description. FIG. 1 has been amended to delete reference numerals 14, 15, and 20. The specification has been amended (at the paragraph beginning on line 11 of page 13) to refer to reference numeral 242 in FIG. 3.

FIG. 1 also has been amended to denote it as prior art, as described in the Brief Description Of The Drawings section of the specification.

Applicants also have amended the specification to correct typographical errors. The amendments of the drawings and specification introduce no new matter.

#### Claim Objections

The Examiner objected to claim 28 because of an informality, viz. "appendage" in line 23 should be changed to --appendage.--. Applicants have amended claim 28 to correct this informality.

The Examiner objected to claim 33 because of an informality, viz. "providing lumen" in line 2 should be changed to --providing a lumen--. Applicants have amended claim 33 to correct this informality.

The Examiner objected to claim 35 because of an informality, viz. "tube" in line 5 should be changed to --tube.--. Applicants have amended claim 35 to correct this informality.

#### Claim Rejections Under 35 U.S.C. § 112

Claims 28-38 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

Claim 28 recites "said sheath assembly" in line 13. The Examiner stated that "there is insufficient antecedent

basis for this limitation in the claim." Applicants have amended claim 28 to replace "said sheath assembly" with "said tube assembly" to more particularly point out and distinctly claim subject matter of applicants' invention. Antecedent basis for "said tube assembly" is present in line 5 of claim 28.

Claim 28 recites "the ostium" in line 18. The Examiner stated that "[t]here is insufficient antecedent basis for this limitation in the claim." Applicants have amended claim 28 to replace "the ostium" with "an ostium" to more particularly point out and distinctly claim the subject matter of applicants' invention.

Claim 29 recites "providing a positioning guide" in line 3. The Examiner stated that "[i]t is unclear whether this is the same structure that is already recited in claim 28 or an additional structure." Applicants have amended claim 29 to replace "wherein providing said catheterization apparatus further comprises providing a positioning guide that is disposed on a positioning tube" with "wherein said providing a catheterization apparatus comprises providing a positioning guide that is disposed on a positioning tube" to more particularly point out and distinctly claim the subject matter of applicants' invention. Antecedent basis for "said

providing a catheterization apparatus" is present in line 4 of claim 28.

Applicants have amended claims 30-35 and 37-38 to more particularly point out and distinctly claim the subject matter of applicants' invention. Applicants have amended claim 30 to depend from claim 29, and to replace "wherein providing said positioning guide further comprises" with "wherein said providing a positioning guide comprises".

Applicants have amended claim 31 to replace "wherein providing said reversibly expandable structure comprises providing at least a preformed wire configuration" with "wherein said providing a positioning guide having a reversibly expandable structure comprises providing a positioning guide having at least a preformed wire configuration".

Applicants have amended claim 32 to replace "wherein providing said reversibly expandable structure comprises providing an inflatable balloon" with "wherein said providing a positioning guide having a reversibly expandable structure comprises providing a positioning guide having an inflatable balloon".

Applicants have amended claim 33 to replace "wherein providing said tube assembly further comprises

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providing lumen" with "wherein said providing a catheterization apparatus comprises providing a lumen.

Applicants have amended claim 34 to replace "wherein providing said tube assembly" with "wherein said providing a catheterization apparatus".

Applicants have amended claim 35 to replace "wherein providing said tube assembly" with "wherein said providing a catheterization apparatus".

Applicants have amended claim 37 to depend from claim 28, and to replace "wherein providing said tube assembly further comprises" with "wherein said providing a catheterization apparatus comprises".

Applicants have amended claim 38 to replace "wherein providing said tube assembly further comprises providing an inflatable structure" with "wherein said providing a catheterization apparatus further comprises providing a securement means having an inflatable structure".

The amendments of the claims introduce no new matter.

#### Claim Rejections Under 35 U.S.C. § 102

Claims 28, 30, and 31-33 were rejected under 35 U.S.C. § 102(e) as being anticipated by Lesh. Claim 28 is

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independent. Claims 30-33 depend directly or indirectly from claim 28. These rejections are respectfully traversed.

Applicants have amended claim 28 to incorporate the subject matter of claim 36 and to more particularly point out and distinctly claim the subject matter of applicants' invention. Applicants have canceled claim 36, and request that the cancellation of claim 36 be without prejudice. Amended claim 28 recites, in part, "providing a catheterization apparatus comprising: a tube assembly... said assembly comprising at least an outer tube [and] a securement means attached to said outer tube...; further advancing said tube assembly to traverse a septum...; deploying said securement means in at least one of said first and second atria; [and] securing said outer tube against motion with respect to said septum...."

Support for the amendments to claim 28 is present, for example, in the specification on page 4, lines 11-30 and on page 12, lines 6-30. The amendments of claim 28 add no new matter.

The Examiner acknowledged on page 5, paragraph 12, of the Office Action that "Lesh does not disclose an outer tube assembly with securement means to engage surface portions of a septum traversed by the outer tube." Applicants respectfully submit, therefore, that Lesh does not



show or suggest providing a securement means and securing the outer tube against motion with respect to the septum as required by claim 28.

In particular, applicants respectfully note that Lesh FIG. 9 shows distal end 83 of catheter 81 breaching septum 86. (See also Lesh at column 10, lines 9-17.) Catheter 81 as shown and described by Lesh is free to move in both directions with respect to septum 86.

Applicants respectfully submit, therefore, that independent claim 28 as amended and dependent claims 30-33, which depend directly or indirectly from claim 28, are not anticipated by Lesh.

Claim Rejections under 35 U.S.C. § 103

Claims 28-31 and 34-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lesh in view of Stevens. These rejections are respectfully traversed. Claims 28-31 and 34-38 depend directly or indirectly from claim 28.

As stated above, amended claim 28 recites, in part, "providing a catheterization apparatus comprising: a tube assembly... said assembly comprising at least an outer tube [and] a securement means attached to said outer tube...;

further advancing said tube assembly to traverse a septum...; deploying said securement means in at least one of said first and second atria; [and] securing said outer tube against motion with respect to said septum...." As mentioned above, the Examiner acknowledged that "Lesh does not disclose an outer tube assembly with securement means to engage surface portions of a septum traversed by the outer tube." (Office Action, page 5, paragraph 12.)

The Examiner alleged that Stevens "teaches that an outer tube with securement means is provided to allow the introduction of instruments for visualization and intervention through the outer tube and to provide a securement means that prevents leakage of blood (Stevens at column 13, lines 24-63)." Applicants respectfully disagree with the Examiner's characterization of Stevens.

Applicants respectfully submit that Stevens teaches the use of "a hemostatic sealing means... [which] functions to seal the penetration around the exterior of shaft 24 to prevent leakage of blood through the penetration from the interior of heart H." (Column 13 lines 44-47.) Stevens further discloses, in column 13 lines 54-57, that "...a pair of balloons 32, 42 may be mounted to shaft 24 spaced slightly apart to provide a seal on both sides of cardiac wall 40...."

The sealing method of Stevens does not show, suggest, or require that shaft 24 be fixed relative to the cardiac wall or septum, nor that it be constrained from moving relative to the wall or septum.

Applicants respectfully assert, therefore, that Stevens teaches a method for sealing a hole in a cardiac wall, but does not teach or suggest "securing [an] outer tube against motion with respect to [a] septum," as required by amended claim 28.

Applicants respectfully submit, therefore, that the teachings of Stevens cannot be combined with the teachings of Lesh to arrive at the applicants' claimed invention and, therefore, that amended claim 28 and claims 29-35 and 37-40, which depend directly or indirectly from claim 28, are not obvious from Lesh in view of Stevens.

#### New Claims 39 and 40

Claims 39 and 40, which depend indirectly from claim 28, have been added to more particularly point out and distinctly claim subject matter that applicants regard as their invention. Support for these claims is found, for example, in the specification in the paragraph beginning on line 17 of page 16, and in the paragraphs beginning on

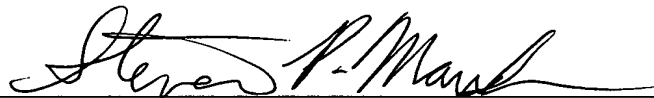
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lines 6, 21, and 31 of page 12. The new claims introduce no new matter.

### Conclusion

For at least the reasons set forth above, applicants respectfully submit that claims 28-35 and 37-40 are patentable and that this application, as amended, is in condition for allowance. Reconsideration and prompt allowance of this application are respectfully requested.

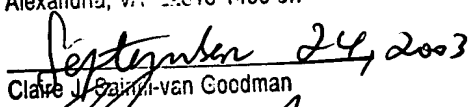
Respectfully submitted,

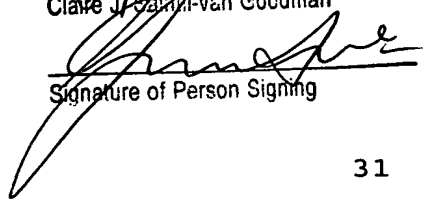


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